REMARKS

The Office Action mailed September 10, 2004 has been carefully considered. Applicants wish to thank the Examiner for the effort in evaluating this application. The following is noted:

Claims 1 through 21 are pending in the present application.

By the present amendment, it is believed that the amended claims have overcome the examiner's rejections as detailed in the following remarks.

Claim Objections

Claims 4 and 6 have been objected to as reciting abbreviations for some active ingredients. These abbreviations are believed by the Applicant to be clear from are art recognized abbreviations that would be clear to a person skilled in the art. Withdrawal of the objections is respectfully requested.

Claim 4 has also been objected to as containing two occurrences of "lipase inhibitor". The attention of the Office is directed to page 7 at line 26, where "lipoprotein lipase inhibitor such as, for example NO 1886" is used to describe a particular embodiment of the invention that is claimed by claim 4. Attention is also directed to page 7 at line38, where "lipase inhibitor wuch as, for example, orlistat" is used to describe another particular embodiment of the invention that is claimed by claim 4. Attention is further directed to page 9 at line 6, where "lipase/amylase inhibitors (e.g. WO 00/40569)" is used to describe still another particular embodiment of the invention that is claimed by claim 4. From reference to the specification at these places, the subject matter being claimed in claim 4 seems clear, and the references to the use of "lipase inhibitor" that are being objected to are distinct aspects of the invention that are being claimed. Withdrawal of this objection is respectfully requested.

Specification

The disclosure has been objected to for several informalities.

A substitute page for page 4 of the specification is included herewith with the names of the amino acids aligned properly in columns.

Substituted pages are submitted herewith for pages 9 and 10 to correct the labeling of Table 1.

Pages 10 and 17 have been objected to as containing blank space. The undersigned practitioner asserts that the space on page 10 is necessary because Table II of page 11 would not fit on page 10. Also, page 17 has blank space because the table on page 18 would not fit on page 17. Reduction of the size of these tables to make them fit in the available blank space would reduce the text and numbers in those tables to the point where they could be difficult for the Office to read.

In the examples at pages 14 and 15 the entries are aligned properly on substitute versions of these pages submitted herewith.

Appropriate correction of the objections raised in the outstanding Office Action, in accordance with the kind suggestions of the Examiner, have been made on the substitute specification pages submitted herewith, and the Applicant respectfully requests the withdrawal of the objections to the specification.

Claim Rejections – 35 USC §112

Claims 1-21 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claims 1 and 3 recited the term C_0 alkyl. Claim 1 has now been amended to change this recitation to C_1 alkyl to correct this obvious error. Claim 3 has now been cancelled, rendering moot its rejection.

Claim 1 has been rejected as containing the term "derivative". The term used in claim 1 that the Office Action refers to is believed to actually be "physiologically functional derivative". That term as used in claim 1 is defined clearly in the specification on page 3 at lines 22 through 24. It is respectfully requested that this rejection be withdrawn in light of the provided definition.

Claim 4 has been rejected regarding the "lipoprotein(a)" limitation. Since claim 4 has been cancelled, this rejection is rendered moot.

Claims 5 and 6 have been rejected regarding the use of the term "normalizes". Since these claims have been cancelled, this rejection is rendered moot.

Claim 9 has been rejected for the use of the term "Caromax®". The Applicant asserts that the specification provides a clear description of what this term refers to on page 9 at lines 20 through 30. The source of this composition of matter is provided, and a reference is given describing this composition of matter is greater detail. Withdrawal of the rejection is respectfully requested.

Claims 11, 13, 15 and 20 have been rejected as being indefinite for not providing a clear interpretation of what is meant by a pharmaceutically effective amount of the compound of formula I with the other active ingredient. It is believed that this is made clear by reference to the table on page 18 of the specification. Attention is drawn to the bottom line, for Group 9. Comparison of the data on this line, compared with the data of lines 2, 3 and 6, shows that the effect of the combination is **synergistic**; that is, it is not simply additive. A person skilled in the art would expect a total effect of 10% plasma cholesterol lowering from the combined treatment with the two compounds. In fact, the combination lowers the plasma cholesterol 19% and this is very surprising and not obvious for a person skilled in the art. Withdrawal of the rejection is respectfully requested.

Double Patenting

Claims 1-7 and 20 have been rejected under the judicially created doctrine of obviousness-type double patenting, over claims 5 and 6 of U.S. Patent No. 6,387,944. It is believed that the present amendment to claim 9 overcomes this rejection, and the presently claimed invention is significantly different from what is claimed in the '944 patent. It is believed that the skilled person would not perceive that the presently claimed invention substantially overlaps that of the '944 patent. Further explanation of why this overlap exists is respectfully requested.

Claims 1-7 and 20 have been rejected under the judicially created doctrine of obviousness-type double patenting, over claims 5 and 6 of U.S. Patent No. 6,221,897. Again, it It is believed that the present amendment to claim 9 overcomes this rejection, and the presently claimed invention is significantly different from what is claimed in the '944 patent. It is believed that the skilled person would not perceive that the presently claimed invention substantially overlaps that of the '897 patent. Further explanation of why this overlap exists is respectfully requested.

Claims 1-7 and 20 have been rejected under the judicially created doctrine of obviousness-type double patenting, over claims 31-40 of co-pending Application No.

10/606,771. Since this is a "provisional" rejection, it is respectfully requested that this rejection be held in abeyance until the claims of the '771 application have been allowed.

Claim Rejections – 35 USC §103

Claims 1-7 and 21 have been rejected under 35 U.S.C. 103(a) as being obvious over Fricke, in combination with AHFS Drug Information 1994, pages 1096-1102. The Applicant respectfully asserts that the synergistic effect outlined above on page 10 of this response overcomes the obviousness rejection. The two references cited in this obviousness rejection, alone or in combination, do not teach or suggest a synergistic effect as demonstrated in the data shown in the table on page 18 of the subject application. Withdrawal of the rejection is respectfully requested.

Claims 1-3, 6-8 and 20 have been rejected under 35 U.S.C. 103(a) as being obvious over Fricke, in combination with Castaner. The Applicant respectfully asserts that the synergistic effect outlined above on page 10 of this response overcomes the obviousness rejection. The two references cited in this obviousness rejection, alone or in combination, do not teach or suggest a synergistic effect as demonstrated in the data shown in the table on page 18 of the subject application. Withdrawal of the rejection is respectfully requested.

Claims 10-19 have been rejected under 35 U.S.C. 103(a) as being obvious over Fricke, in combination with AHFS Drug Information 1994, pages 1096-1102. The Applicant respectfully asserts that the synergistic effect outlined above on page 10 of this response overcomes the obviousness rejection. The two references cited in this obviousness rejection, alone or in combination, do not teach or suggest a synergistic effect as demonstrated in the data shown in the table on page 18 of the subject application. Withdrawal of the rejection is respectfully requested.

Applicants reserve the right to pursue the cancelled subject matter in a timely filed Continuation application.

It is believed that no new matter has been introduced by the present amendments of the specification and the claims.

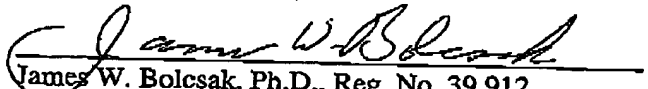
Conclusion

In view of the foregoing discussion, it is believed that all the pending claims, as amended, fully comply with the legal requirements. Reconsideration and allowance of the application with pending claims are earnestly solicited.

Enclosed herewith is a Petition under 37 C.F.R.§ 1.136(a) to extend the time for response for three months, or until March 10, 2005. It is believed that no additional fees and charges are required at this time in connection with the application; however, if any fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No.18-1982.

If prosecution can be advanced by direct telephone contact with the undersigned, the Office is invited to call the practitioner directly at the number provided below.

Respectfully submitted,



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